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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,111

09/08/2003

Francesco Salituro

VPI/98-11 DIV

9944

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01/05/2006

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EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/658,111

**Applicant(s)**

SALITURO ET AL.

**Examiner**

Deepak Rao

**Art Unit**

1624

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-25 and 30 are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-25, 30 are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This office action is in response to the amendment filed on December 13, 2005.

Claims 11-25 and 30 are pending in this application.

Upon reconsideration, the finality of the previous office action is withdrawn, in view of the following rejections under new grounds.

#### ***Withdrawn Rejections/Objections:***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

#### ***The following rejections are under new grounds:***

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-25 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (I), does not reasonably provide enablement for the instantly claimed compounds of formula (III) or the tautomers thereof or the pharmaceutically acceptable salts thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The specification fails to enable the preparation of the entire scope of the claimed compounds. The process scheme in Example 1 of the specification provides the essential starting materials to prepare the claimed compounds of formula (I) having a bicyclic ring system, however, there is no disclosure of the sources of starting materials needed to prepare for compounds of formula (I) or the tautomers thereof. The specification does not provide any explanation or sources required to prepare the compounds of formula (III) having a monocyclic pyridyl ring. The only disclosed synthetic example is drawn to a bicyclic compound and the specification does not provide the required starting materials to prepare the instantly claimed compounds of formula (III), to enable a person of ordinary skill to prepare the compounds of the claimed structural formula. In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention. The starting material sources necessary to obtain the instant compounds must have been available as of the filing date

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in order to provide an enabling disclosure. See *In re Howarth*, 654 F.2d 103, 210 USPQ 689 (CCPA 1981); *Ex parte Moersch*, 104 USPQ 122 (POBA 1954). Applicants should show that the sources of these starting materials was common knowledge or readily available at the time of filing.

The specification fails to enable one skilled in the art to use the claimed compounds. The use disclosed in the specification is as p38 inhibitors useful to treat inflammatory diseases, etc., see page 20. Test assays to measure the activity are provided at pages 34+ of the specification, however, none of the instantly claimed compounds of formula (III) have been tested for activity. All the compounds actually tested are structurally very different from the compounds commensurate in scope of the claims. Receptor activity is generally unpredictable and highly structure specific area. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo undue amount of experimentation to use the claimed compounds as p38 inhibitors. There is no reasonable likelihood of success in the use of the compounds commensurate in scope of the claims for the disclosed activity and resulting therapeutic applications.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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1. Claim 17 recites the limitation "The compound according to claim 11 ...." and discloses 'Compound 15'. There is insufficient antecedent basis for 'compound 15' in compounds of claim 11. As per claim 11, Q<sub>2</sub> is always substituted with J wherein J is a C<sub>1</sub>-C<sub>4</sub> alkyl substituted with substituents selected from A, -T-C(O)R' or -OPO<sub>3</sub>H<sub>2</sub>. Compound 15 of claim 17 has a group -CH<sub>2</sub>-O-C(O)-CH<sub>2</sub>-NH<sub>2</sub> substituted on Q<sub>2</sub> ring and it does not correspond to any of the groups defined under J.
2. Claim 20 recites the limitation "The compound according to claim 11 ...." and discloses 'Compound 18'. There is insufficient antecedent basis for 'compound 18' in compounds of claim 11. As per claim 11, Q<sub>2</sub> is always substituted with J wherein J is a C<sub>1</sub>-C<sub>4</sub> alkyl substituted with substituents selected from A, -T-C(O)R' or -OPO<sub>3</sub>H<sub>2</sub>. Compound 18 of claim 20 has a group -CH<sub>2</sub>-NH-CH<sub>2</sub>-C(O)-OEt substituted on Q<sub>2</sub> ring and it does not correspond to any of the groups defined under J.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

December 30, 2005